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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,736	02/20/2002	Justin R. Fallon	BURF-P02-006	2816
28120	7590	11/04/2005		
FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			EXAMINER CHERNYSHEV, OLGA N	
			ART UNIT	PAPER NUMBER
			1649	
DATE MAILED: 11/04/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/081,736

Applicant(s)

FALLON ET AL.

Examiner

Olga N. Chernyshev

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13, 15, 16, 38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13, 15-16 and 38-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 09, 2005 has been entered.

### ***Formal matters***

2. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

### ***Response to Amendment***

3. Claims 13 and 39 have been amended as requested in the amendment filed on September 09, 2005. Following the amendment, claims 13, 15-16 and 38-39 are pending in the instant application.

Claims 13, 15-16 and 38-39 are under examination in the instant office action.

4. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

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6. Applicant's arguments filed on September 09, 2005 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

***Claim Rejections - 35 USC § 102***

7. Claims 13, 15-16 and 32-38, as amended, stand rejected under 35 U.S.C. 102(b) as being anticipated by Ruoslahti et al., US Patent No. 5,654,270 for reasons of record in section 10 of Paper mailed on September 20, 2004 and in section 6 of Paper mailed on April 04, 2005.

Applicant traverses the rejection on the premises "that Ruoslahti et al. fail to satisfy the criteria necessary to anticipate the claimed invention [for failing] to teach or suggest each and every limitation of the present claims" (bottom at page 4 of the Response). Applicant further refers to *In re Robertson*, *Ex parte Levy* and *In re Marshall* to argue that inherency may not be established by probability and must flow from the teachings of the prior art (pages 6-7 of the Response). Applicant's review of the issue of anticipation, the case law that has been cited and the holding that is found in that case law is not disputed. The only point of disagreement appears to be the interpretation of what constitutes inherent teaching of prior art reference.

The instant invention is based on discovery that "biglycan binds directly to the MuSK receptor; biglycan directly induces the tyrosine phosphorylation of MuSK; biglycan potentiates agrin-induced phosphorylation of MuSK" (top at page 12 of the instant specification), and, as such, regulates muscular innervation by participating in neuromuscular formation. However, the instant claims are broadly drawn to a method for activating a membrane of a cell by contacting the cell with biglycan. In accordance with MPEP 2111, when analyzing the claimed subject matter, the claims are to be given their broadest reasonable interpretation that is consistent with

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the specification (see MPEP 2111 [R-1], which states that claims must be given their broadest reasonable interpretation

“During patent examination, the pending claims must be "given \*>their< broadest reasonable interpretation consistent with the specification." *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550- 51 (CCPA 1969)”.

As such, the broadest reasonable interpretation of the claimed invention is one of a method comprising a step of contacting biglycan with a membrane of any cell. As fully explained in the previous office actions of record, because the patent of Ruoslahti et al. expressly describes administration of biglycan to a wound as a method for prevention or reduction of scarring (see column 3, Summary of the Invention, for example), and since MuSK is present not only on muscular cells but is expressed in other tissues (see middle at page 16 of the instant specification), one would reasonably expect that such contact of biglycan and cell membrane would lead to activation of MuSK, absence evidence to the contrary.

MPEP 2112.02 states “when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. *In re May*, 574 F.2d 1082,1090, 197 USPQ 601, 607 (CCPA 1978)”. Applicant argues that “a comparison of the Ruoslahti et al. reference to the present disclosure demonstrates that one of ordinary skill in the art who attempted to follow the teachings of Ruoslahti et al. would be unlikely to develop a method that meets the elements of the present claims” (middle at

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page 5 of the Response). However, the claimed method is limited to essentially two “elements”. The first is a contact of biglycan and a membrane of a cell, and publication of Ruoslahti et al. fully anticipates this element. Second element is activation of MuSK present on cell membrane, which is achieved upon contact of biglycan and cell membrane comprising MuSK. The Examiner maintains that by contacting biglycan with a cell membrane, MuSK is activated. Applicant reliance to *In re Marshall* (middle at page 6 of the Response) is not applicable in the instant case because the instant claims are not directed to a method of treatment of a specific condition that follows activation of MuSK but are limited to a method for activating a cell membrane by contact with biglycan. One of skill in the art readily appreciates that unless activation of MuSK can be achieved only by specific molecular embodiments of biglycan or by using specific concentrations of biglycan, within particular cell types, etc., contact of biglycan and a cell membrane comprising MuSK would lead to activation of MuSK. Therefore, publication of Ruoslahti et al. meets all the limitations of the instant invention, as currently claimed.

It is noted that Applicant refers to activation of postsynaptic membrane by biglycan (see pages 5-6 of the Response), while the instant claims, as amended, do not specifically recite postsynaptic membranes.

Therefore, for reasons fully explained in previous office communications of record and reasons above, the instant rejection is maintained.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 recites the limitation "postsynaptic membrane" in claim 13. There is insufficient antecedent basis for this limitation in the claim.

### *Conclusion*

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870.

The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Olga N. Chernyshev, Ph.D.

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Primary Examiner  
Art Unit 1649

October 28, 2005